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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,906	09/15/2003	Rong-Hwa Lin	A0871.70001US00	1268

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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
11/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/662,906	LIN ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *1-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group II (claim 39) and further elects the species of (A) homomeric and (D) anti-PSGL-1 antibody in the Response to Restriction Requirement, filed 09/13/2007.

Further, the following is noted.
In response to Item 2 on page 2 of the Restriction Requirement,
the examiner invited applicant to clarify whether the recitation "binds at least two PSGL-1 proteins" is intended to simply indicate that the multimeric compound [sic] binds two (2) PSGL-1 molecules or whether the claims encompass two types of PSGL-1 proteins (emphasis original).
In response, applicant submits these can but may not necessarily be mutually exclusive alternatives. Accordingly, Applicant respectfully refrains from making a clarification as invited by the examiner.

It is noted that applicant had previously elected Group I in the Response to Restriction Requirement, filed 11/03/2006 in the Reply to Notice of Non-Responsive Reply to Restriction Requirement, filed 03/05/2007.

However, given applicant's most current election of Group II in the Response to Restriction Requirement, filed 09/13/2007,
Claims 1-38 (Group I) have been withdrawn from consideration as being drawn to the non-elected invention.

Further as acknowledged above, applicant's election of Group II in the in the Response to Restriction Requirement, filed 09/13/2007, is acknowledged.
Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 39 is under consideration in the instant application.

2. Priority.

The effective filing date of the instant claims is deemed to be the filing date of the instant application USSN 10/662,906, filed 09/15/2003;
as the previous priority applications do not appear to provide sufficient written description for the claimed "multimeric compound comprises two polypeptide chains, each of the polypeptide chains comprising (i) a binding domain that binds to PSGL-1, and (ii) a heterologous amino acid sequences, wherein the polypeptide chains are linked via the heterologous amino acid sequence", including as the multimeric compound reads on the elected invention of "anti-PSGL-1 antibodies".

Therefore, the "a kit comprising ... " and "instructions for use ... " for the claimed "multimeric compound" recited in instant claim 39 have an effective filing date of the instant claims is deemed to be the filing date of the instant application USSN 10/662,906, filed 09/15/2003.

If applicant disagrees, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the parent application. Applicant is invited to verify the priority date of the instant claims, including written support and enablement under 35 USC 112, first paragraph.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

4. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected. Appropriate corrections are required.

Trademarks should be capitalized or accompanied by the ® or ™ symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Appropriate corrections are required

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 39 is rejected under 35 U.S.C. § 103(a) as being unpatentable Lazarovits et al. (US 2004/0002450 A1) (1449; #A17) AND/OR Levanon et al. (US 2004/0001839 A1) in view of the well known convention in the art at the time the invention was made to place therapeutic components, including therapeutic antibodies, in a kit for convenience and economy, as evidenced by Anderson et al. (U.S. Patent No. 6,348,581) AND/OR Hockfield et al. (U.S. Patent No. 6,884,619).

Lazarovits et al. teach methods of treating various therapeutic conditions, including inflammation, autoimmunity and cancer, with PSGL-1-specific antibodies (e.g., see entire document, including paragraphs [0055] – [0057]; Summary of the Invention on paragraphs [0059] – [0144]; Detailed Description of the Invention), including the Y1, Y17 and KPL1 epitopic specificities (e.g., see Selectins and PSGL-1 on paragraphs [0029] – [0042]; Summary of the Invention; Detailed Description of the Invention; and Examples), including antibody constructs (e.g., see paragraphs [0474] – [0523]), including multivalent or multimeric antibody constructs (e.g., see paragraphs [0047] – [0052], [0480], [0485] – [0507]; Examples 8 – 16 on pages 38-40).

Although Lazarovits et al. does not teach kits comprising "instructions" per se, Lazarovits et al. does teach diagnostic kits comprising anti-PSGL-1 antibodies (e.g., see paragraphs [0140], [0144], [0520] and [0524]) as well as a number of therapeutic utilities encompassing the use of anti-PSGL-1 antibodies (e.g., see paragraphs [0055], [0131] – [0139], [0509] –[0548]).

Levanon et al. teach methods of treating various therapeutic conditions, including inflammation, autoimmunity and cancer with PSGL-1-specific antibodies (e.g., see entire document, including paragraphs [0055] – [0057]; Summary of the Invention on paragraphs [0059] – [0144]; Detailed Description of the Invention), including the Y1, Y17 and KPL1 epitopic specificities (e.g., see Selectins and PSGL-1 on paragraphs [0029] – [0042]; Summary of the Invention; Detailed Description of the Invention; and Examples), including antibody constructs (e.g., see paragraphs [0448] – [0493]), including multivalent or multimeric antibody constructs (e.g., see paragraphs [0047] – [0052], Summary of the Invention on paragraphs [0059] – [117], [0454], [0459] – [0493]; Examples 8 – 16 on pages 36-38).

Although Levanon et al. does not teach kits comprising "instructions" per se, Levanon et al. does teach kits including diagnostic kits comprising anti-PSGL-1 antibodies (e.g., see paragraphs [0117], [0494] and [0498]) as well as a number of therapeutic utilities encompassing the use of anti-PSGL-1 antibodies (e.g., see paragraphs [0054] – [0055], [0116], [0504] –[0522]).

Therefore, both Lazarovits et al. and Levanon et al. teach multimeric anti-PSGL-1 antibodies comprising two polypeptides and a heterologous amino acid sequence encompassed by the claimed invention.

As noted above, both Lazarovits et al. and Levanon et al. teach providing such anti-PSGL-1 antibodies in kits as well as describing a number of therapeutic uses for said anti-PSGL-1 antibodies.

Lazarovits et al. and Levanon et al. teach differ from the claimed invention by not describing "instructions for use in kits" comprising antibodies.

First of all, it is noted that where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. See In re Ngai and Lin, 70 USPQ2d (Fed. Cir. 2004) and MPEP 2112.01.

In addition, the following has been provided show that it was well known in the art at the time the invention was made by the ordinary artisan to place therapeutic components, including therapeutic antibodies, in a kit for convenience and economy, as evidenced by Anderson et al. (U.S. Patent No. 6,348,581) AND/OR Hockfield et al. (U.S. Patent No. 6,884,619).

Anderson et al. teach kits comprising therapeutic antibodies as well as other ingredients to produce a formulation suitable for administration, including a preference for the kit to comprise instructions for reconstituting and using the antibody (e.g., see columns 14-15, overlapping paragraph).

In a similar vein, Hockfield et al. teach various kits comprising various compounds, including antibodies that include instructional materials which describe the use of the compound to perform described methods (e.g., see VII. Kits on columns 45-46).

One of ordinary skill would have found it obvious to package ingredients and instructions for use into a kit for convenience, economy and the expected benefit of optimizing standardization of preparing and using therapeutic antibodies of interest at the time the invention was made.

It is proper to "take account of the inferences and creative steps that a person of ordinary skill in the art would employ". See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385, 1396 (2007).

One of ordinary skill in the art at the time the invention was made would have been motivated to provide multimeric antibodies comprising anti-PSGL-1 antibodies, including those anti-PSGL-1 antibodies with the Y1, Y17 and KPL1 epitopic specificities, in kits comprising said antibodies and instructions for convenience, economy and the expected benefit of optimizing standardization of preparing and using therapeutic antibodies of interest at the time the invention was made, given the teachings of the prior art of inhibiting various inflammatory, autoimmune or cancer conditions targeted by PSGL-1 antagonists, as taught by Lazarovits et al. and Levanon et al. A person of ordinary skill in the art at the time the invention was made would have been motivated by taking the advantages of the specificities and properties of the highly inhibitory properties of the Y1, Y17 and KPL1 anti-PSGL-1 antibody epitopic specificities, including their multimeric forms, to treat various inflammatory, autoimmune and cancer conditions with an expectation of success, since such properties and advantages are consistent with human therapeutic regimens associated with treating said conditions at the time the invention was made. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdigital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Given that the prior art goal was to provide antagonistic anti-PSGL-1 antibodies to treat a variety of inflammatory, autoimmune and cancer conditions,

incorporating multimeric antagonistic anti-PSGL-1 antibodies in kits comprising said antibodies and instructions for use would have been routine to the ordinary artisan at the time the invention was made and therefore obvious in designing such kits for convenience, economy and the expected benefit of optimizing standardization of preparing and using therapeutic antibodies of interest at the time the invention was made.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 39 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable

over claims 9-10 of USSN 11/125,837

in view of Lazarovits et al. (US 2004/0002450 A1) (1449; #A17) AND/OR Levanon et al. (US 2004/0001839 A1) and the well known convention in the art at the time the invention was made to place therapeutic components, including therapeutic antibodies, in a kit for convenience and economy, as evidenced by Anderson et al. (U.S. Patent No. 6,348,581) AND/OR Hockfield et al. (U.S. Patent No. 6,884,619) for the reasons above in Section 6.

The copending claims differ from the instant claims by not reciting multimeric anti-PSGL-1 antibodies per se and providing said anti-PSGL-1 antibodies in kits comprising said multimeric anti-PSGL-1 antibodies and instructions for use.

However, the copending anti-PSGL-1 antibodies encompass single chain antibodies (e.g., see page 9, paragraph 1 of the specification of USSN 11/125,837)

As indicated above in Section 6, multimeric anti-PSGL-1 antibodies, particularly multimeric anti-PSGL-1 antibodies comprising single chain antibodies were obvious to the ordinary artisan at the time the invention was made.

As indicated above in Section 6, providing therapeutic antibodies in kits comprising instructions for use were obvious to the ordinary artisan at the time the invention was made.

8. Claim 39 is directed to an invention not patentably distinct from claims 9-10 of commonly assigned USSN 11/125,837 for the reasons set forth above in Section 7.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned USSN 10/662,906, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

9. No claim allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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